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nutrients received from a supplier or prepared by an infant formula manufacturer.

Production aggregate means a quantity of product, or, in the case of an infant formula produced by continuous process, a specific identified amount produced in a unit of time, that is intended to have uniform composition, character, and quality, within specified limits, and is produced according to a master manufacturing order.

Production unit means a specific quantity of an infant formula produced during a single cycle of manufacture that has uniform composition, character, and quality, within specified limits.

Production unit number or production aggregate number means any distinctive combination of letters, numbers, symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a production aggregate or a production unit of infant formula can be determined.

Quality factors means those factors necessary to demonstrate the safety of the infant formula and the bioavailability of its nutrients, as prepared for market and when fed as the sole source of nutrition, to ensure the healthy growth of infants.

Representative sample means a sample that consists of a number of units that are drawn based on rational criteria, such as random sampling, and intended to ensure that the sample accurately portrays the material being sampled.

Shall is used to state mandatory requirements.

[79 FR 8059, Feb. 10, 2014, as amended at 79 FR 33070, June 10, 2014]

Subpart B—Current Good Manufacturing Practice

§ 106.5 Current good manufacturing practice.

(a) The regulations set forth in this subpart define the minimum current good manufacturing practices that are to be used in, and the facilities or controls that are to be used for, the manufacture, processing, packing, or holding of an infant formula. Compliance with these provisions is necessary to ensure that such infant formula provides the nutrients required under §107.100 of this chapter and is manufactured in a manner designed to prevent its adulteration. A liquid infant formula that is a thermally processed low-acid food packaged in a hermetically sealed container is also subject to the regulations in part 113 of this chapter, and an infant formula that is an acidified food, as defined in §114.3(b) of this chapter, is also subject to the regulations in part 114 of this chapter.

(b) The failure to comply with any regulation in this subpart in the manufacture, processing, packing, or holding of an infant formula shall render such infant formula adulterated under section 412(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(a)(3)); the failure to comply with any regulation in part 113 of this chapter in the manufacture, processing, packing, or holding of a liquid infant formula shall render such infant formula adulterated under section 412(a)(3); and the failure to comply with any regulation in part 114 of this chapter in the manufacture, processing, packing, or holding of an infant formula that is an acidified food shall render such infant formula adulterated under section 412(a)(3).

§ 106.6 Production and in-process control system.

(a) A manufacturer shall conform to the requirements of this subpart by implementing a system of production and in-process controls. This production and in-process control system shall cover all stages of processing, from the receipt and acceptance of the raw materials, ingredients, and components through the storage and distribution of the finished product and shall be designed to ensure that all the requirements of this subpart are met.

(b) The production and in-process control system shall be set out in a written plan or set of procedures that is designed to ensure that an infant formula is manufactured in a manner that will prevent adulteration of the infant formula.

(c) At any point, step, or stage in the production process where control is necessary to prevent adulteration, a manufacturer shall:

(1) Establish specifications to be met;